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Responsible Conduct of Research (RCR)

NAVY MEDICINE EAST, PORTSMOUTH, VA
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Presentation originally created by Jerlyn Tolentino,
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Purpose

- **Department of Defense (DoD) Regulations.** DoD requires the implementation of policies and procedures to ensure public trust and foster integrity in research activities and respond to allegations of misconduct consistent with applicable law
  - DoD Directive 3216.2 and DoD Instruction 3210.7

- **Department of the Navy Regulations.** Navy Medicine East activity staff who are engaged in research or who have the authority to approve research should be aware of their ethical responsibilities as stated in
  - BUMEDINST 6500.3

RCR Education Requirements

- RCR education is required for all NME's Command staff involved in research, as well as Department Heads, Residency Program Directors and Assistant Directors, and Directors whose staff are involved in research.
- Initial education is required and must be renewed every 3 years.
- RCR education is different from CITI training.
  - Both are required for new and continuing review of human subjects and animal research studies reviewed by the NMCP IRB.
- Recommend incorporating RCR and CITI training into TY intern/resident orientations.

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RCR Education Requirements

- You must complete at least 4 hours of instruction, including:
  1. Review BUMEDINST 6500.3
  2. Review this PowerPoint (required)
  3. Watch the interactive video (required)– 'The Lab" which can be found online at http://ori.hhs.gov/TheLab.
  4. Read/review/discuss "On Being a Scientist", which can be downloaded from (required). http://www.nap.edu/catalog.php?record_id=12192
  5. Read/review/discuss some of the articles on RCR included on the RCR SharePoint at NME (optional). [see next slides]
     a. Departments are encouraged to use some of these articles or other articles for journal clubs (can focus on potential RCR issues in any article of choosing).
     b. Departments should/are encouraged to obtain CME/CEU credit for journal club review of these articles and/or the RCR requirements.
  6. Have face to face discussion with the a research mentor or other qualified person in your department regarding RCR topics listed above (required).

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Journal Club Articles

1. Davis MS, Riske-Morris M, Diaz SR. Causal factors implicated in research misconduct: evidence from ORI case files. Science and engineering ethics. 2007 Dec;13(4):395-414. http://www.sel.eesc.usp.br/informatica/graduacao/material/etica/private/causal_factors_implicated_in_research_misconduct_-_evidence_from_ori_case_files.pdf

2. Habermann B, Broome M, Pryor ER, Ziner KW. Research coordinators' experiences with scientific misconduct and research integrity. Nursing research. 2010 Jan-Feb;59(1):51-7. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2877381/

3. Heckman JD. Retractions. The Journal of Bone & Joint Surgery. 2009;91(4):965 http://dx.doi.org/

4. Reuben SS, Ekman EF. The Effect of Cyclooxygenase-2 Inhibition on Analgesia and Spinal Fusion. The Journal of Bone & Joint Surgery. 2005;87(3):536-42. **http://dx.doi.org/10.2106/JBJS.D.02283** [example of a retracted article. Read and discuss how these fabricated data could have had implications on your patients]

5. Marcus A. German Medical Board Issues Sweeping Findings in Boldt Case: Ninety studies implicated in probe, might require retraction. 2011 [cited; Available from:

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Journal Club Articles

6. Marret E, Elia N, Dahl JB, et al. Susceptibility to fraud in systematic reviews: lessons from the Reuben case. Anesthesiology. 2009 Dec;111(6):1279-89. http://journals.lww.com/anesthesiology/pages/articleviewer.aspx?year=2009&issue=12000&article=00023&type=abstract

7. Roig M. Avoiding plagiarism, self-plagiarism, and other questionable writing practices: A guide to ethical writing. In: Office of Research Integrity. http://ori.hhs.gov/sites/default/files/plagiarism.pdf

8. Slesser AA, Qureshi YA. The implications of fraud in medical and scientific research. World journal of surgery. 2009 Nov;33(11):2355-9. http://download.springer.com/static/pdf/560/art%253A10.1007%252Fs00268-009-0201-5.pdf?auth66=1354817873_88856e8a5d88463d8c139aaaaa80e46a&ext=.pdf

9. Steneck NH. Fostering integrity in research: definitions, current knowledge, and future directions. Science and engineering ethics. 2006 Jan;12(1):53-74. http://www.engr.uky.edu/~gedney/DGS/currentGrads/SciEngEthics_06.pdf

10. Editors ICoM. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication. ICMJE; 2010. http://www.icmje.org/urm_full.pdf

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About this Course

- The goal of this course is to promote responsible conduct of research and help those involved in research activities to become proactive and better prepared to deal with any issues that may arise during the course of a research project.
- The course is intended to increase users' awareness of responsible conduct of research issues.
- Each section will provide a brief introduction and an example to nine RCR topics.
- More detailed information on each topic can be found in the Resources sub-section, which will provide links to documents, videos, and additional reading materials.
- After meeting your RCR requirements please submit an electronic copy of the Completion Certificate (**from the Helm or from end of this slide presentation-see next bullet)** to your departmental training officer and forward a copy to the Clinical Investigations Department, Research Facilitation Division.
- When submitting a new or continuing review for an IRB protocol it is recommended personnel submit a copy of the RCR training certificate along with other required documentation.

INTRODUCTION TO RCR

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Public Responsibility

- Researchers have an obligation to conduct research in a responsible manner to their colleagues and to the public.

- Researchers trust that the results other researchers report are valid.

- Society trusts that the results of research are honest and unbiased.

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Research Ethics

- Research ethics is honesty in the planning, conduct, and reporting of research, including:
  - Protection of human and animal subjects in the conduct of research
  - Collection, use, and interpretation of research data
  - Methods for reporting and reviewing research plans or findings
  - Mentor-trainee relationships
  - Accuracy in representing contributions to research proposals and reports
  - Fairness in peer review
  - Collegiality in scientific interactions, including communications and sharing of resources
  - Transparency in conflicts of interest or potential conflicts of interest
  - Adherence to the mutual responsibilities between investigators and their research teams

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Research Ethics

- The domain of research ethics is intended to include nothing less than the fostering of research that protects the interest of the public, the subjects of research, and the researchers themselves.

- The remainder of the presentation will guide you through areas of the research process where you may be faced with ethical challenges.

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Resources

- **Introduction to the Responsible Conduct of Research** by Nicholas Steneck available as free download at: http://ori.hhs.gov/publications/ori_intro_text.shtml

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Induction of DNA methylation and gene silencing by short interfering RNAs in human cells
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RESEARCH MISCONDUCT AND POLICIES FOR HANDLING MISCONDUCT

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MIT Research Misconduct Example

Professor dismissed for research misconduct

MIT announced last week that Luk Van Parijs, an associate professor in biology, has been terminated for research misconduct.

The university launched an investigation in August of 2004 when members of his research group brought allegations of research misconduct by Van Parijs to the attention of the MIT administration. During the course of the investigation, Van Parijs admitted to fabricating and falsifying research data in a paper and several manuscripts and grant applications. The investigation found no evidence that his co-authors or the members of his research group were involved in the misconduct or were aware of it when it occurred.

"In this case a single individual admitted that he fabricated and falsified data," said Associate Provost and Vice President for Research Alice Gast, who oversees allegations of scientific and academic misconduct at MIT. "We are very concerned that his actions not cast a shadow over his co-authors or members of his research group, none of whom was involved in the misconduct.

"Integrity in research and scholarship is a bedrock principle of MIT. Research misconduct violates this principle and MIT takes any allegations of research misconduct very seriously," said Gast. "We acted immediately when the allegations were brought to our attention and began a very thorough and confidential investigation to determine the extent of the misconduct and whether other individuals were involved."

Van Parijs was placed on leave immediately after the allegations were reported and has had no access to his lab or office since then.

Van Parijs' area of research is in the use of short-interference RNA (or RNAi) in studying disease mechanisms, especially in autoimmune diseases. It can be categorized as basic scientific research related to normal immune cell function and defects in these cells during disease development. His work did not involve medical treatments. RNAi is an important area of research, and scientists in the field of RNAi, including many researchers at MIT, continue to make legitimate and important advances, some of which are related to the treatment of such diseases as cancer, diabetes and arthritis.

MIT is working in collaboration with the co-authors and in consultation with the Office of Research Integrity in the National Institutes of Health, the federal agency that oversees these investigations, to see that retractions are published. In cases where research involves federal funding, as some of Van Parijs' work did, federal regulations specify how allegations of scientific misconduct should be investigated. Under MIT's own policies for such investigations, which follow the federal requirements, the associate provost and vice president for research appoints an impartial committee to investigate the allegations.

Federal and MIT rules require that investigations be conducted in strict confidence to protect the integrity of the review process and to avoid unjustified damage to the reputations of individuals, including innocent colleagues and collaborators.

The final report of the investigation will be sent to the Office of Research Integrity, which will conduct its own confidential review of the matter and make the findings public when that review is complete.

MIT TechTalk Vol 50(7), 2 Nov 2005

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Research Misconduct

- "Research misconduct is defined as **fabrication**, **falsification**, or **plagiarism** in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or differences of opinion. It must represent a significant departure from accepted practices of the relevant research community. It must have been committed intentionally, knowingly, or recklessly."

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Research Misconduct

- **Fabrication**: making up data or results and recording or reporting them.
- **Falsification**: manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- **Plagiarism**: appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

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Research Misconduct

- Constitutes a breach of the professional ethics standards for research in all disciplines.
- Violates the public trust, as well as the professional trust within the institution.
- Where research misconduct has occurred, institutions must take all necessary and substantive steps to ameliorate the situation and attempt to restore professional trust.

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Procedures for Handling Misconduct

- **Initial Reporting:** Personnel who become aware of potential research misconduct must report such concerns to the command's research integrity leader.

- **Inquiry:** The command's research integrity leader makes a preliminary, informal determination to determine if the reported instance falls under research misconduct definitions or has any substance.

- **Investigation:** If initial inquiry determines that there has been evidence of research misconduct, the commanding officer notifies the individual and the matter proceeds to formal research misconduct investigation.

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Procedures for Handling Misconduct

- **Adjudication**: If an investigation determines that research misconduct has occurred, the commanding officer will notify the individual the outcome of the investigation and appropriate corrective actions, if any, are determined.

- **Appeal:** Individuals determined to have committed research misconduct can appeal the results of the investigation or adjudication, within 30 days of each action.

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Resources

- **NSF (2005): Sec. 689.1 Definitions. Part 689 – Research Misconduct**. Subpart A – General. Chapter VI – National Science Foundation. Title 45 – Public Welfare. 45CFR689.1(a). http://www.nsf.gov/oig/resmisreg.pdf

- OSTP (2000): **Federal Policy on Research Misconduct: Notification of Final Policy**. Federal Register December 6, 2000 65(235): 76260-76264. http://ori.hhs.gov/policies/fed_research_misconduct.shtml

- **Research Misconduct Resources** from the Office of Research Integrity can be accessed at http://ori.hhs.gov/education/products/rcr_misconduct.shtml

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RESEARCH INVOLVING HUMAN SUBJECTS

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Human Subject Research

- A majority of research at NMCP involves the use of human subjects.
- Therefore, it is important for NMCP researchers to understand the rules and regulations that govern human subject research and to ensure that the risks of the project do not outweigh the benefits.
- In depth education and training of human subject research is covered in the Collaborative Institutional Training Initiative (CITI) module that all investigators are required to complete before beginning work on a research project.

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Resources

- **Federal Policy for the Protection of Human Subjects**, 45 CFR 46, Subpart A (2005).
  http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

- **Office for Human Research Protections**, HHS. Home Page.
  http://www.hhs.gov/ohrp/

- **Department of the Navy Human Research Protection Program** (DONHRPP).
  http://www.med.navy.mil/bumed/humanresearch/resource/Pages/DONHRPPGuidance.aspx

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CONFLICT OF INTEREST AND COMMITMENT

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Conflicts of interest bedevil psychiatric drug research

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Enlarge Getty Images 2004 file photo

Bottles of antidepressant pills Paxil, Lexapro, Effexor and Zoloft. Last year, antidepressants brought in $9.6 billion, says IMS HEALTH.

By Marilyn Elias, USA TODAY

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Does it matter if most of the experts who are creating definitions of mental disorders, and standards for the best way to treat them, receive money from pharmaceutical companies?

That question is hotly debated in scientific journals, but it isn't just academic. It also cuts to the core of public welfare by making it possible for financial profit to affect decisions about who needs treatment, whether they are prescribed medicine and which ones, says Lisa Cosgrove, a psychologist at the University of Massachusetts-Boston.

Lisa Cosgrove

University of Massachusetts

Critics such as Cosgrove say there's a damaging conflict of interest in the financial ties between drug companies and leaders who are revising the "bible" of psychiatric diagnoses, the Diagnostic and Statistical Manual of Mental Disorders (DSM-V), as well as guidelines on the best treatments.

About 160 experts appointed by the American Psychiatric Association are doing the heavy lifting on the updated manual, expected in 2012. They're tops in their field, and because industry pays for two-thirds of research, many of them consult for drug companies or do corporate-funded studies, says Darrel Regier, research director for the group. "There's this assumption that a tie with a company is evidence for bias. But these people can be objective," he says.

Darrel Regier

American Psychiatric

This is the first time the psychiatry association has required members of 13 working groups on diagnoses, as well as the leadership task force, to publicly disclose all industry ties.

Sixty-eight percent of task-force members report economic ties with drug companies, Cosgrove says. And of those with links, about four out of five don't just get research funding, they're on corporate boards, hold stock or collect money as advisers, she says. She and Harvard Medical School psychiatrist Harold Bursztajn have criticized these ties in *The New England Journal of Medicine* and *Psychiatric Times*.

Even small changes in the symptoms for diagnosis of a problem can greatly increase prescriptions for drugs, Cosgrove says, so anyone who could benefit from changes has a potential conflict.

More than half of the members on the 13 working groups also have such ties, according to Cosgrove's analysis. She says no group should have a majority with drug company links.

But Regier argues: "We want the best people. We don't want quotas or an artificial litmus test." He says potential conflicts are limited by a rule that panel members can't receive more than $10,000 from drug companies while at work on the new DSM.

The $10,000 limit "is not a particularly sensible idea," says Daniel Carlat, a Tufts psychiatrist who publishes an independent monthly, *The Carlat Psychiatry Report*, on trends in the field. "They've had lucrative relationships in the past, and they know they're going right back to them."

Carlat says it's unrealistic to exclude people with industry-research funding, but he favors limits on those who give promotional talks on drugs, "the real hired guns," and others with a direct financial interest in firms. "Maybe no more than 30%, maybe no more than 50%. These panels shouldn't be stacked the way they are now," he says.

Another flash point: clinical guidelines. Cosgrove led a study on 20 authors of treatment standards for major depression, bipolar disorder and schizophrenia: 90% of them had financial ties to firms that make drugs recommended for the disorder.

But the psychiatry group casts a net to hundreds of reviewers for every guideline, says John McIntyre, who chairs the guidelines committee. The depression and bipolar standards are being updated, "and we've gotten thousands of comments online,"

Regier says. So any bias gets diluted by diverse voices, McIntyre says; plus, the guidelines are based on evidence.

But there's the rub, critics say, because drug company-funded studies consistently come out with more positive results for their drug than do independent studies.

"In psychiatry, many diseases are treated equally well with medication or therapy," Carlat says. "But the guidelines tend to be biased toward medication" because it's costly to make and study drugs.

Much is at stake. Antipsychotics, which had $14.6 billion in sales last year, were the top-selling class of U.S. medicines; antidepressants brought in $9.6 billion, says IMS HEALTH.

The debate over whether economic self-interest may bias the DSM and treatment guidelines leads to a root issue: Drug companies pay for gathering evidence, and there's no major alternative on the horizon, says Paul Appelbaum, an expert on ethics in psychiatry at Columbia University. He's concerned about potential conflicts. But other financing suggestions — for example, companies contributing money for studies run independently by the government — have gone nowhere, he says.

"We're a capitalist society built on competition, and that has led to many successes," Appelbaum says. "But this conflict-of-interest issue shows the side effects of the system we have."

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Conflict of Interest

- A conflict of interest arises when a financial or other personal consideration has the potential to compromise or bias professional judgment and objectivity.

- A common concern is that financial interest in the outcomes of research may be compromised by personal interest.

- "***Significant financial interest***" is broadly defined as anything of monetary value that could include salary or payment for services from an external institution, any equity (stock) interests, and any intellectual-property rights.

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Disclosure of Conflict of Interest

- When a potential conflict of interest is identified, it is imperative that a thorough analysis is conducted and that the potential conflict of interest is disclosed and reported appropriately.

- All investigators are required to complete and sign a ‘Conflict of Interest’ disclosure document with all Institutional Review Board (IRB) applications.

- A number of journals now require researchers to disclose real or potential financial conflicts.

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Conflicts of Commitment

- Conflicts of commitment arise from situations that place competing demands on researchers' time and loyalties, such as:
  - Working on one or more funded projects
  - Preparing to submit a request for a new project
  - Teaching and advising students
  - Clinical responsibilities
  - Attending professional meetings and giving lectures
  - Serving as a peer reviewer
  - Sitting on advisory boards
  - Working as a paid consultant, officer, or employee in a private company

- Care needs to be taken to assure that these commitments do not inappropriately interfere with one another.

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Resources

- **The Joint Ethics Regulation, Department of Defense 5500.7-R**, can be accessed at *www.dod.gov/dodgc/**defense_ethics/ethics_regulation**/dir550007.pdf*

- National Science Foundation (1995): **NSF Investigator Financial Disclosure Policy**. Federal Register July 11, 1995 60(132) .
  http://www.nsf.gov/pubs/stis1996/iin117/.txt

- DeAngelis CD, Fontanarosa PB, Flanagin A. **Reporting financial conflicts of interest and relationships between investigators and research sponsors**. *JAMA*. 2001;286(1):89-91.

- DeAngelis CD. **Conflict of Interest and the Public Trust** [Editorial]. *JAMA*. 2002; 284(7);2237.

- Friedman PJ. **The Impact of Conflict of Interest on Trust in Science**. *Sci Eng Ethics.* 2002;8(3):413-420.

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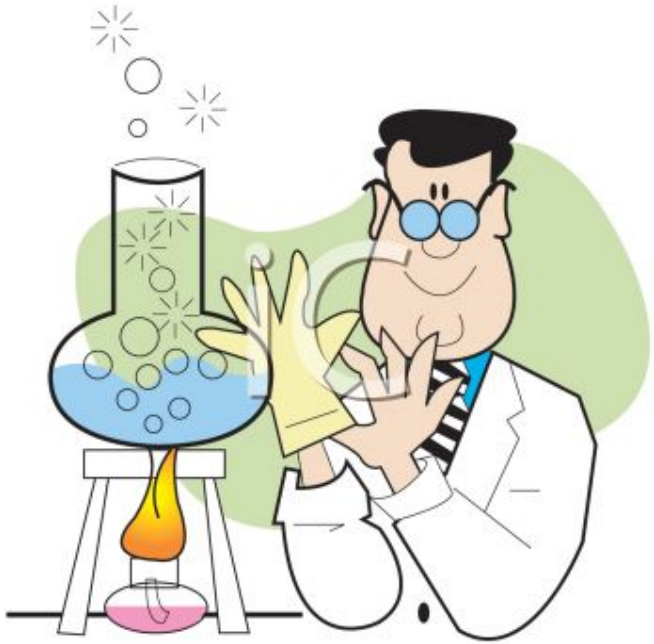

DATA OWNERSHIP, ACQUISITION, MANAGEMENT, AND SHARING

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Example

Case Vignette: Collecting Valid Data

Part of the data collection methodology for Dr. Smith's study includes distributing a 12-page self-administered questionnaire to participants; they must fill out and initial each page of the questionnaire to confirm completion.

One day on his way home from conducting an interview with a subject, the Research Assistant, Joel, needed to write directions for a friend and he reached in his bag and grabbed the first piece of paper that he could find. Joel accidentally ripped the back page off of one of the completed questionnaires to write the directions, which he then gave to his friend. He didn't realize this until a few hours later, when he was reviewing the data that he had collected that day.

Joel thought that he remembered the participant's answers on the last page of the survey, since they were mostly demographic questions.

What should Joel do?

__ Staple on a new page and fill out the subject's responses, since he remembers them.
__ Contact the subject and ask her to complete the last page of the questionnaire again.
__ Omit the participant's questionnaire from the study, his/her partial data is invalid.
__ Just pretend like he doesn't know what happened to the last page.

Answer: Omit the participant's questionnaire from the study, his/her partial data is invalid. This is Joel's best option - if he were to attempt to collect the data again from the subject, the subject would be responding in a different time and mood than when the original interview occurred. As part of responsible data management, honesty about the mishap is the best way to maintain the validity of the data and to clarify that the data were not tampered with or falsified in any way. Read on to learn more about collecting valid data.

From Clinical Tools, Inc. Funded by Office of Research Integrity (DHHS)

Overview

- Appropriate data management efforts are essential to protect research integrity and intellectual property, ensure confidentiality, and comply with sponsor requirements.

- To conduct research responsibly, researchers must understand how to treat data correctly

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Data Ownership

- Who owns the data that you will be collecting?
- Unless otherwise specified in a Collaborative Research and Development Agreement (CRADA) or Memorandum of Understanding (MOU)/ Memorandum of Agreement (MOA) all data belong to the Federal Government.
- It is particularly important to establish who owns the data if you are working collaboratively with another institution.

Data Acquisition

- To help ensure integrity during the data collection process consider the following:
  - Make sure to use appropriate and reliable methods
  - Quality research requires attention to detail
  - Make sure to secure the proper authorization and approvals before beginning data collection:
    - IRB approval
    - Information contained in some libraries, databases, and archives
    - Information posted on some Web sites
    - Published photographs and other published information
    - Other copyrighted or patented processes or materials
  - Make sure that data are properly recorded

Data Management and Protection

- Meticulous data management practices support the validity of findings.
- Data should be properly stored to protect from accidental damage, loss, or theft.
- Government files should not be stored in personally owned computers. Electronic files should be stored in CD’s or in Government approved computers/data-bases.
- Data containing protected personal identifiable information (PPI) must be safeguarded to ensure against improper disclosure.
- Data should be retained for a reasonable period of time to allow other researchers to check results or to use the data for other purposes.

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Data Sharing

- Data should be made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data.

- Data sharing is important to:
  - Promote open scientific inquiry
  - Encourage diversity of analysis and opinion
  - Promote new research
  - Facilitate the testing of new or alternative hypotheses and methods of analysis
  - Support studies on data collection methods and measurement
  - Facilitate education of new researchers
  - Enable the exploration of topics not envisioned by the initial investigators
  - Permits the creation of new datasets when data from multiple sources are combined

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Data Sharing

- After results are published, it is expected that all the information about that experiment, including the final data, should be freely available for other researchers to check and use.

- Some journals formally require that data published in articles be available to other researchers upon request or stored in public databases.

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Data Management Plan

- To help ensure that data is treated correctly, it is a good idea to develop a thoughtful data management plan.

Data Management Plan

- Determine what data will be collected
- How will data be recorded
- Who will perform the collection
- What analysis methodologies will be used
- What criteria will be established to accept or reject data
- What results will be published
- When and where results will be submitted for publication
- How, where and for how long the records will be retained
- Who will have record-keeping responsibility
- What results might be shared
- When and how results could be shared
- Who has decisional authority for the sharing of data/results

Data Management

- It is incumbent upon Government employees to protect the privacy of individuals and the interests of the Government. Personnel should have an understanding of procedures to protect Government interests. Institutions must implement procedures and methods to ensure these interests are, in fact, protected.

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Resources

- **15 U.S.C. 290e,** can be accessed at http://www.law.cornell.edu/uscode/uscode15/usc_sec_15_00000290---e000-.html
- **28 USC 1498**, can be accessed at http://www.law.cornell.edu/uscode/28/usc_sec_28_00001498----000-.html
- **5 USC § 552a**, can be accessed at http://www.law.cornell.edu/uscode/html/uscode05/usc_sec_05_00000552---a000-.html
- **35 USC § 200-212**, can be accessed at http://www.law.cornell.edu/uscode/html/uscode35/usc_sup_01_35_10_II_20_18.html
- **17 U.S.C. 105**, can be accessed at http://www.law.cornell.edu/uscode/17/105.html
- **37 CFR § 401**, can be accessed at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&tpl=/ecfrbrowse/Title37/37cfr401_main_02.tpl
- **SECNAVINST 5211.5E**, can be accessed at http://doni.daps.dla.mil/Directives/05000%20General%20Management%20Security%20and%20Safety%20Services/05-200%20Management%20Program%20and%20Techniques%20Services/5211.5E.pdf

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MENTOR-TRAINEE RELATIONSHIPS

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Example

Dr. Smith is an Assistant Professor and Director of the Fellowship Training Program in Pediatric Hematology and Oncology at a hospital with a well-known research program. He has an NIH grant funded research, but has had trouble completing his research and writing results because of his clinical duties. A colleague suggests that he could get more research done if he could attract a fellow to work on his project and all he has to do is be a mentor. When a new group of fellows begins Dr. Smith recruits Dr. Marsh to work on his project.

Dr. Smith's clinical duties and other commitments prevents him from spending time with Dr. Marsh. Instead of teaching her research methodology he tells her to enroll in a Course on Research Methodology. They initially plan to meet for an hour twice a week, but he ends up cancelling 4-5 meetings each month. Nevertheless, over the next 18-months Dr Marsh is resourceful and finds other professors and post-doctoral fellows to train her and she ends up producing important research results. When Dr. Smith discovers this, he starts to take more interest in her and is now meeting with her 2-3 times weekly, reviewing data, and commenting frequently on her experiments.

Her results are now ready to be written and submitted to a peer reviewed journal publication. Dr. Smith still needs a few publications to get tenure. So Dr Smith suggests that he be the first author on two of the planned papers, and that she could be the first author on the other two. Although Dr. Marsh did all of the initial work independently, Dr. Smith reasons that he has been more involved with the research in the last months, and after all, it was his project and NIH grant that paid for the research.

Modified from Children's Hospital LA Responsible Conduct of Research Training website:
http://www.chla.org/site/c.ipINKTOAJsG/b.5019595/k.FFD3/Responsible_Conduct_of_Research_Training.htm

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Mentoring

- Mentoring is a process of continuing education and enrichment that takes place in the professional relationship between a seasoned or more senior expert, and one who is new or relatively more junior.
- Effective mentoring is essential to promote a positive attitude and an understanding of the responsible conduct of research.
- A mentor teaches responsible conduct explicitly and by example.
- An absence of adequate mentoring can have significant consequences for the integrity of research.

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Mentoring

- The mentor-mentee relationship, as shown in our example, is complex and brings into play potential conflicts:
  - How much time should each devote to each other?
  - Who gets credit for ideas that take shape during the course of a shared experiment?
  - Who owns the results?
  - When does a trainee become an independent researcher?

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Mentoring

- A mentor's role is to provide advice, help, and encouragement, to guide rather than decide for the trainee.

- The trainees' responsibility is to seek out mentors who can provide the expertise and experience to help fulfill the trainee's needs and to act based on their own values

Mentoring

- Good mentoring should begin with:
  - A clear understanding of mutual responsibilities
  - A commitment to maintain a productive and supportive research environment
  - Proper supervision and review
  - An understanding that the main purpose of the relationship is to prepare trainees to become successful researchers
  - A decision on time commitment
  - Establishing how responsibilities are shared or divided in the research setting
  - An understanding of how data should be recorded and interpreted
  - Determining how credit (authorship and ownership) will be assigned

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Resources

- Columbia University**: Responsible Conduct of Research Mentoring Module** http://ori.hhs.gov/education/products/columbia_wbt/rcr_mentoring/

- Lee A, Dennis C, Campbell P. ***Nature*'s guide for mentors**. *Nature*. June 2007;447(14): 791-797. http://www.nature.com/nature/journal/v447/n7146/full/447791a.html

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- Gabriele, E. (2010). **The Tradition of Mentoring Part II: Leadership and Mentoring in the Culture of Healthcare**. *Proceedings of the 2009 International Ethics Conference at the University of Botswana. Journal of Research Administration.* Volume XLI. Number 2. (pp 61-73).

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COLLABORATIVE RESEARCH

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Example

Case Study

Sharon, Ben, and Terra met during a late-night discussion at a professional meeting. They share a common interest in learning disorders but come from different scientific backgrounds. Sharon works at the cutting edge of brain imaging technology. Ben is an educational psychologist interested in pre-school children in inner cities. Terra has been putting her knowledge as a physiologist to work exploring the effects of alternative medicines.

As late night turns to early morning, the newly met trio begins to see benefits from working together and starts sketching out a grant proposal. The scientific ideas quickly fall into place, but some of the logistics raise questions that need answers.

Who should submit the proposal, through which university?

Do all three need to get IRB approval to work on the project?

What will happen if their work has practical applications?

How should they go about answering these questions? Are there other important questions that should be asked as well?

From Office of Research Integrity, Introduction to the Responsible Conduct of Research, by Nicholas H. Steneck

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Collaboration

- Collaborations are welcome and encouraged.
- Responsible collaborations are defined by openness and early, on-going communication.
- There should be mutual understanding of what is to be exchanged through the collaboration, how the research will be undertaken, and how the products of the collaboration will be shared.

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Roles and relationships

- Before beginning a collaboration make sure that all parties have an understanding of:
  - The goals and anticipated outcomes of the project
  - The role of each partner
  - How data will be collected, stored, and shared
  - How changes in research design will be made
  - Who will be responsible for drafting publications
  - Criteria that will be used to identify and rank contributing authors
  - Who will be responsible for submitting reports and meeting other requirements
  - Who will be responsible for or have the authority to speak publicly for the collaboration
  - How intellectual property rights and ownership issues will be resolved
  - How collaboration can be changed and when it will come to an end

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Management of Collaborations

- **Financial:** Commands cannot accept funds from external collaborators. Support from external institutions must come in the form of equipment, supplies, personnel, etc.
- **Training and Supervision:** All research staff should be properly trained and supervised.
- **Formal Agreements:** CRADA's, MOUs/MOAs should be made between NME and any external collaborators if one does not already exist. This will help outline roles and responsibilities of each party.
- **Compliance:** All research institutions involved in the collaboration must ensure that they are in compliance with specific research regulations.

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Resources

- **VA/DoD Collaboration Guidebook for Healthcare Research**, can be accessed at http://www.research.va.gov/va-dod/

- **Marine Corps Order 3900.18**, can be accessed at http://www.onr.navy.mil/en/About-ONR/compliance-protections/Research-Protections/~/media/Files/34/MCO-390018.ashx

- Macrina FL et al. (1995): **Dynamic Issues in Scientific Integrity: Collaborative Research**. American Academy of Microbiology, Washington, D.C.

  http://academy.asm.org/images/stories/documents/dynamicissuesinscientificintegrity.pdf

- Government-University-Industry Research Roundtable, NetLibrary Inc. **Overcoming Barriers to Collaborative Research**: Report of a Workshop, Washington, DC: National Academy Press, 1999.

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Who should be an author?

PUBLICATION AND AUTHORSHIP

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You have been recently hired as an Assistant Professor in the Division of Pediatric Pulmonology at Childrens Hospital. You would like to investigate how infant lung disease affects lung function in later life. Your research study measured pulmonary function tests and exercise stress tests in 25 children, age 12-14 years, who were born prematurely and treated with mechanical assisted ventilation for respiratory distress syndrome in the neonatal intensive care unit, and you compared these results to those of 20 control children. You found a significant decrement in lung and exercise function in your study group. Successful completion of this study did require the help of several people. You are now writing a manuscript you intend to submit for peer-review publication. You will be the first author on your paper, but the following people have asked if they could be coauthors on your paper:

Doctor Hill: one of your colleagues who actively participated in helping you perform the study. For example, if you were on service when a patient came in for testing, she was present at the exercise stress test. You discussed the paper with her at several times when the study was being formulated and when analyzing data. She made a number of important suggestions, which improved the final study.

Daniel Herbert: a pulmonary function laboratory technician who performed the studies as part of his job. He did not do anything above and beyond his job for which he is paid.

Susan Maule: a pulmonary function laboratory technician who performed the studies. Although this is part of her job, for which she was paid, she volunteered to come in on nights and week-ends to study some patients who could not come in during the day. She did not get paid for these extra studies. She also helped with some data analysis, and she was a resource for technical aspects of the testing. She is hoping to go to medical school in a few years.

Doctor Marks: one of your colleagues and a good friend. He did not participate in the study, but he suggested that if you put his name on all of your papers as an author, and if he puts your name on all of his papers as an author, you will both benefit by increasing your CVs.

Doctor Pavlak: Chief of Neonatology and Clinical Director of the Neonatal Intensive Care Unit where the patients were all treated during their neonatal illness. You discussed the study with her in order to obtain her approval to access the patients. She did nothing else in performance of the study.

Doctor Sturdy: Chief of Pediatric Pulmonology, your boss. He did nothing on your study, but his name is traditionally put on all papers coming from the Division as senior author.

QUESTION: Who should be offered authorship on your paper and why? If you would not offer authorship to an individual above, what would that person have to have done to deserve authorship?

Modified from Children's Hospital LA Responsible Conduct of Research Training website:
http://www.chla.org/site/c.iplNKTOAJsG/b.5019595/k.FFD3/Responsible_Conduct_of_Research_Training.htm

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Publication

- Staff are encouraged to submit authored works for publication to exchange information, promote professional growth and scholarship, and enhance one's development and that of Navy Medicine.

- Prior to submission of authored work for publication (oral presentation, poster, or manuscript), Navy approval is required per **BUMEDINST 5721.3C** and applicable command instruction if available.

- **Authored wor**k means any clinical, professional, research-related written document or slide show, intended to be published or otherwise presented to the general public or professional audience outside your command. This includes any work that is to be transmitted via the internet, mass broadcast, or mass e-mail where the general public may have access.

- Disclaimer of Government Views: Authored works must contain the following disclaimer: "The views expressed in this article are those of the author and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, nor the U.S. Government."

- Human Research Protection: Work reflecting human subjects must include acknowledgements that the research has received applicable review board approval.

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Authorship

- According to the International Committee of Medical Journal Editors (ICMJE), an “author” is generally considered to be someone who has made substantive intellectual contributions to a published study.

- Key aspects of authorship include:
  - Substantial contributions to the conception, design, acquisition of data, or analysis and interpretation of data
  - Drafting of the article or significant contribution to critical review and revision of draft manuscript

- It is important that the members of the research team understand and agree to responsible authorship principles.

- Government employees cannot receive compensation for authored works relating to their official duties per 5 CFR §2635.807

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Ethical Problems with Authorship

- Due to the pressure researchers are often under to publish the following ethical issues may arise:
  - **Paper Inflation:** many are tempted to garner as much out of a given research effort as possible. Which sometimes results in the temptation to undergo duplicate publishing. Duplicate publication may results in skewing of the weight of results and most journals do not prefer to publish works that have already been published.
  - **Fragmentary Publication or Self-Plagiarism:** some authors break up related efforts to submit a series of papers or reprocess their earlier work so it appears original. Authors should shape a publication to present a complete description of a particular study's efforts.
  - **Plagiarism/Falsification/Fabrication of Data:** these constitute research misconduct and severely undermine research integrity and the public trust. They can lead to flawed knowledge that can impact the lives of individuals in wrongful, even harmful or destructive ways. Authors must be vigilant against plagiarism, falsification, or fabrication of information/data in published works or in presentations.
  - **Citations:** an author should cite publications that influence the reason for the study, study design, or interpretation of results. An author has an obligation to perform a literature search to find, and then cite, the original publications that describe closely related work. Proper citations help guard against plagiarism. Quotations should include a citation of the source. Private communications should only be referred to with permission. Care must be taken to avoid disclosure of personally identifiable information (PII).

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Authorship and Publication

- Authorship and good publication practices are extremely important because they give credit where credit is due. Authorship carries corresponding obligations regarding issues of fairness and responsibility. These include proper attribution of authorship, order of authors, and other aspects of responsible authorship.

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Resources

- **5 CFR §2635.807**, can be accessed at http://edocket.access.gpo.gov/cfr_2002/janqtr/5cfr2635.807.htm
- **42 CFR 50 and 93**, can be accessed at http://ori.hhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf
- **DODINST 3210.7**,
- **SECNAVINST 5720.44B**
- Houk, VT., Thacker, SB (1990) **The Responsibilities of Authorship**. In Editorial Policy Committee oof the Council of Biology Editors, editors. Ethics and Policy of Scientific Publication. Bethesda, MD: Council of biology Editors, 181-184.
- **International Committee of Medical Journal Editors (ICMJE)**
  http://www.icmje.org/ethical_4conflicts.html
- **Responsible Authorship Quick Guide: Detecting Common Mistakes & Considering Dilemmas in Responsible Authorship**
  http://ori.hhs.gov/education/products/niu_authorship/index.htm
- **Authorship Task force (2000): Is it Time to Update the Tradition of Authorship in Scientific Publications?** Council of Science Editors (formerly council of Biology Editors)
  http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3376
- Horton R, Smith R (1996): **Signing up for Authorship.** Lancet 347 (9004):780.
- Rennie D, Flanagin A, Yank V (2000): **The Contributions of Authors.** JAMA 284(1): 89-91.
- Yank V, Rennie D (1999): **Disclosure of Researcher Contributions: a Study of Original Research Articles in The Lancet.** Annals of Internal Medicine 130(8):661-70.

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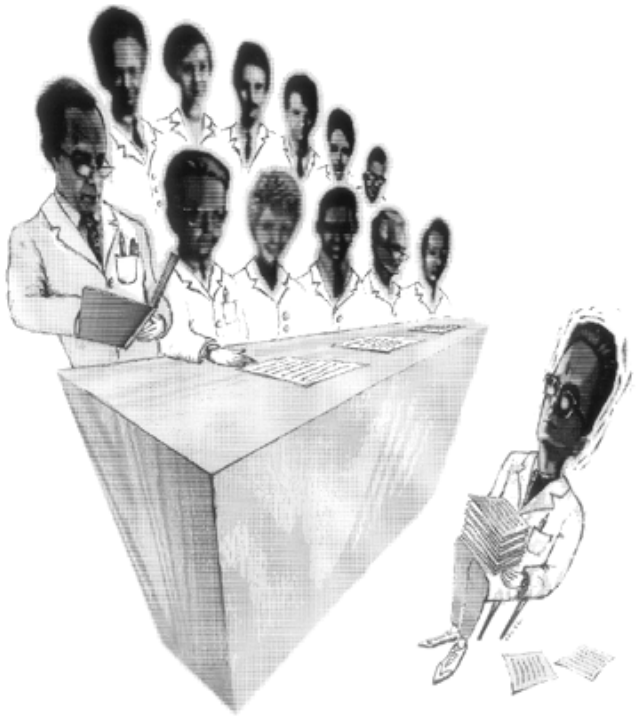

PEER REVIEW

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Example

Case Study

Dr. Sung L. is struggling with the decision whether to agree to review the work of an advanced graduate student at another university for publication in the major journal in his field. He is familiar with the student's work and attended a session several months ago at which she presented a brief report on her work. It clearly overlaps with his research in a number of ways, which is one reason he has been asked to serve as a reviewer.

Dr. L. knows he is qualified to do the review and is confident he can provide an objective, constructive judgment of the students's work. However, since his students are working on similar problems, he is concerned about the appearance of a conflict of interest. In addition, he is not sure he wants to learn more about the work in question until he publishes his own work, to avoid later charges that he unfairly used some of the student's ideas. Finally, there is the matter of yet another lost weekend doing the review, when his department chair has already told him to cut down on unpaid professional service.

Should Dr. L. agree to do the review?

If he is uncertain about his responsibilities, where can he get advice?

Would the situation be different if he had been asked to review the student's work for an appointment or promotion decision?

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Peer Review

- Peer review is expert critique of either a scientific or academic treatise, such as an article prepared or submitted for publication, a grant proposal, or a clinical research protocol, or of an investigator's research program, as in a site visit and is an essential component of the conduct of science and the humanities.

- Peer review has been one of the chief means of critical examination and scrutiny necessary to ensure continued academic and professional excellence.

- Quality peer review relies on professional expertise and integrity to overcome the inherent subjectivity of reviewing others' work.

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Peer Review Guidelines

- Timely
  - Reviewers should make every effort to complete a review in the time requested.
- Competence
  - Reviewers who realize that their expertise is limited have a responsibility to make their degree of competence clear to the editor.
- Constructive
  - Reviewers' comments should acknowledge positive aspects of the material under review, assess negative aspects constructively, and indicate clearly the improvements needed.
- Free from personal bias or conflict of interest and commitment
  - Reviewers' comments and conclusions should be based on a consideration of the facts, exclusive of personal or professional bias.
- Respectful of the need for confidentiality
  - A reviewer should not take advantage of material available through the privileged communication of peer review.

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Resources

- **5 USC 2635**
- **42 CFR 52h** can be accessed at: http://www.access.gpo.gov/nara/cfr/waisidx_03/42cfr52h_03.html
- Joint Ethics Regulation, **DoD 5500.7-R**
- **Peer Review Process**. Office of Extramural Research. National Institutes of Health: http://grants.nih.gov/grants/peer_review_process.htm
- **Office of Research Integrity Peer Review Resources**: http://ori.dhhs.gov/education/products/yale/
- **Nature's peer review debate**: http://www.nature.com/nature/peerreview/debate/index.html
- Rockwell, Sarah. **Ethics of Peer Review: A Guide for Manuscript Reviewers**. Yale University. As found on the Education – RCR Resource Products. Office of Research Integrity, US Department of Health and Human Services. Rockville, MD. http://ori.dhhs.gov/education/products/yale/

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THE END

- Thank you for taking the time to review this presentation.
- We hope that this presentation was able to offer you an introductory look at the responsible conduct of research and get you thinking about the various ethical dilemmas you may face while conducting research.
- Please complete the Certificate of Completion at the end, print, and provide a copy to your departmental training officer/petty officer.
  - Training Officers should enter training completion into CID training database & forward certificates to The Regional Research Integrity Leader @ carolyn.m.medina.civ@mail.mil .

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Signature on this certificate attests to completion of at least 4 hours of instruction,
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